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A prospective randomised, double-blind, placebo controlled trial to assess the respiratory effects of buprenorphine versus morphine in anaethetised patients

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
21/07/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0205120616

Study information

Scientific Title

Study objectives
This study is designed to investigate the effects of buprenorphine and morphine on respiratory parameters and in the event of changes occurring, the use of reversibility by naloxone (an opioid antagonist).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
Buprenorphine and morphine vs placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

buprenorphine and morphine

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/02/2003

Completion date
31/07/2003

Eligibility

Key inclusion criteria
Patients that will have an operation lasting more than 30 min that require general anaesthetic, from Barts Hospital main theatres.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Aim to recruit 90 patients.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
07/02/2003

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthetics
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	The study was presented to and accepted by the Anaesthetic Research Society, UK in December - Meeting in Leeds. The published abstract is cited as: Mehta V, Phillips JP, Wantman AC, Ratcliffe SH, van Raders PA, Langford RM. Investigation of buprenorphine induced respiratory depression in anaesthetised patients and its reversibility. British J Anaesthesia. 2005; 94: 399-400. See	02/03/2008		No	No